

October 12, 2004

Division of Dockets Management  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

RE: Docket No. 2004N-0081, Use of Materials Derived From Cattle in Human Food and Cosmetics

To Whom It May Concern:

The Animal Welfare Trust (AWT), a non-profit organization located in Mamaroneck, NY, appreciates the opportunity to submit comments on the U.S. Food and Drug Administration's (FDA) interim final rule on the Use of Materials Derived From Cattle in Human Food and Cosmetics ("interim final rule"). 69 Fed. Reg. 42288 (July 14, 2004). This interim final rule prohibits the use of certain categories of materials obtained from cattle. For the sake of human health and safety, and animal welfare, AWT encourages the FDA to expand the rule to prohibit the use of all materials from all species of non-ambulatory livestock in human foods and cosmetics.

The threat to human safety from the use of non-ambulatory animal material was brought to national attention in December 2003, when the first known case of bovine spongiform encephalopathy (BSE) in the U.S. was discovered. BSE, belonging to a family of diseases known as transmissible spongiform encephalopathies (TSEs), has caused multiple deaths in the United Kingdom and other countries, and is the likely cause of a new variant of Creutzfeldt-Jakob disease (vCJD) in humans. Worldwide, there have been thousands of known cases of BSE. In the United Kingdom, since 1986, 185,000 cattle were diagnosed with the disease. Department for Environment, Food, and Rural Affairs, United Kingdom. 2004.

Cows, sheep, pigs, and other animals can harbor TSEs. As mentioned in the interim rule, TSEs are characterized by a long incubation period, then a course of neurological symptoms, followed by death. Non-ambulatory animals should be excluded from the food supply because they are more likely than healthy animals to develop disorders such as BSE. These disorders are difficult to diagnose solely by physical examination, and testing every animal may not detect all variants of disease.

BSE is not the only disease that non-ambulatory animals are more likely than healthy ones to carry. Meat from downed animals has an increased risk for containing pathogens such as *Salmonella* and *E. coli*. Researchers have found *E. coli* to be more common in non-ambulatory versus healthy cows at slaughter. *Applied and Environmental Microbiology*;

2003; 69: 4683. Also, outbreaks of Salmonella Newport have been traced to meat produced from slaughtered dairy cows and to processing plants that slaughter a higher proportion of downed animals. *New England Journal of Medicine*;1987; 316:565; *Journal of the American Medical Association*;2002; 288:951.

Alongside the issue of human safety is that of animal welfare. Non-ambulatory livestock are routinely dragged during transport to the slaughterhouse, prodded with electric shocks, kicked, pushed, and are not provided with adequate food, water, and veterinary care. This treatment has been recognized to be inhumane by organizations such as the American Veterinary Medical Association which holds the position that “[a]t no time is a nonambulatory animal to be dragged.” See <http://www.avma.org/policies/animalwelfare.asp#food>.

A ban on all non-ambulatory animal materials is not only supported by many meat producers, animal welfare groups, and trade organizations, but also by the general public and many legislators. A September 2003 Zogby Poll reported that 77% of those surveyed found that it is unacceptable that downed animals are being used for human food. A handful of states including Indiana, Washington, Oregon, Colorado, and California have enacted legislation restricting the transportation and/or marketing of non-ambulatory animals. At the federal level, recently the Downed Animal Protection Act (H.R. 2519 and S. 1298), which would prohibit the marketing and slaughter for human food of all critically ill and injured animals, received much support in Congress falling only a few votes short of passage. Also, several restaurants including McDonald’s, Burger King, and Wendy’s have discontinued buying meat from downed animals for their hamburgers.

Additionally, no significant economic hardship would come from a complete ban on non-ambulatory animal parts use in products regulated by the FDA. There are an estimated 195,000 number of downed cattle per year in the U.S. Hansen, Don and Bridges, Victoria, *A Survey Description of Down-cows and Cows with Progressive or Non-progressive Neurological Signs Compatible with a TSE from Veterinary-client Herd in 38 States*; *The Bovine Practitioner*; 33(2); 179-87, 1999. In a 1999 study by the California Department of Food and Agriculture, it was found that a net average of only \$28.70 was realized for each downer cow leaving the farm. U.S. Animal Health Association, Report of the Committee on Animal Welfare, 1999 Committee Reports, *available at* <http://www.usaha.org/reports/reports99/r99anwel.html>.

In conclusion, AWT urges the FDA to ban all human foods and cosmetics products containing ingredients from slaughtered non-ambulatory cattle and other animals. This would work to the benefit of human safety and animal welfare. In addition, the ban would mirror public concerns and would not create undue economic hardships.

Respectfully submitted,

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